Receipt date: 11/17/2003

10714689 - GAU: 1648

#### **PATENT**

#### IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicants: Sheng C. Lou, et al.

Serial No.: (not yet assigned)

Divisional of application Serial No.: 09731,126; filed 12/6/00; Examiner J. Parkin; Group Art Unit

1648

Filed: November  $\frac{1}{2}$ , 2003

Title: MONOCLONAL ANTIBODIES TO HUMAN IMMUNODEFICIENCY VIRUS

AND USES THEREOF

Attorney Docket No.: 6755.US.D1

Group Art Unit: (not yet assigned)

EXPRESS MAIL NO.: EV314259884US

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#### INFORMATION DISCLOSURE STATEMENT

MS Patent Application Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

The following information is submitted, pursuant to 37 CFR §§1.97-1.98 in accordance with Applicant's duty of disclosure under 37 CFR §1.56. This submission is not intended to constitute an admission that any patent, publication or other information cited herein is "prior art" as to the invention claimed. In accordance with 37 CFR §§1.97(g)-(h), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that other material information as defined by 37 CFR §1.56(a) exists.

Applicants submit herewith Form PTO-1449 listing the references known to them. Applicants respectfully request that the Examiner (1) initial each reference listed on the enclosed Form PTO-1449 indicating that the Examiner has considered and made those references of record in this application and (2) return a copy of the initialed Form PTO-1449 to Applicants. Copies of references were previously submitted in U.S. Serial No. 09/731,126, filed December 6, 2000, from which this divisional application claims priority.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits under 37 CFR §1.97(b). Accordingly, no charge is required.

Respectfully submitted, Sheng C. Lou, et al.

ABBOTT LABORATORIES

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Cheryl L. Becker

Registration No. 35,441 Attorney for Applicants Receipt date: 11/17/2003

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	C2	Minassian, A.A, et al. Type 2 Core Proteins Proceedings of the na	Cross-Reactivity	With HI	V Type 1 and 9	Simian Im	muno	deficiency	Virus,"	
	C3	Zolla-Pazner, Susan, e Immunology Letters,	et al., "The Implic	ation of	Antigenic Dive	ersity for	Vaccin	ne Develor	oment,"	<del></del> -
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<del></del>	A2	4,888,290	12-19-89		ertright, et al.		<u> </u>			
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		OTHER DOCUMENT	FS (Including A	Autho	or, Title, Date, Pla	ce of Put	olication)			
	Cl	Allain, et al., The Lancet, in Haemophiliacs, ii:1233-		rkers	in Early Stages of	Human l	mmunode	ficiency Vi	rus Infe	ection
	C2	Barin, et al., Science, Virus AIDS Patients, 228:1094-1	Envelope Prote	ein of	HTLV-III Represe	nts Major	Target A	ntigen for .	Antibod	ies in
·	C3	Barin, et al., The Lancet, S Residents of West Africa, 2	erological Evid		for Virus Related t	o Simian	T-Lympho	tropic Ret	rovirus	III in
	C4	Bowen, et al., Annals of	Internal Medic	ine,	Transmission of H	luman In	ımunodefi	ciency Vir	us (HI	V) by
		Transplantation: Clinical Ann. Of Int. Med. 108:46-4	Aspects and Tin	ne Co	urse Analysis of Vi	ral Antige	enemia an	d Antibody	Produ	ction,
	2060d5000000	-Rith-Bendomand-Pitti-van-	Knippenberg, ed	ه ۱۸۰۸ خولو	<del>ol. 15 Elsevier, Am</del>	sterdam	/JSP/	05/3	0/10	
	C6	Charneau, et al., Virology, of a New HIV-1 Group, 20:			pe Sequence of a H	lighly Div	ergent HI	V-1 Isolate	e: Defin	nition
	C7	Clavel, et al., <u>Science</u> , <i>Isol</i> 346 (1986)			an Retrovirus from	West Afr	ica Patien	ts with All	OS, 233	:343-
	C8	Clavel, et al., <u>Nature</u> , <i>Mole</i> 324:691-695 (1986)	cular Cloning a	and P	olymorphism of the	Human .	Immune D	eficiency l	Virus Ty	ре 2,
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	(Use several sheets if necessary)	FILING DATE	GROUP
(37 CFR 1.98 (b))	•	November 17, 2003	

## OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

С9	Coffin, Science, HIV Population Dynamic. Therapy, 267:483-489 (1995)	cs in Vivo: Implications for Genetic Variation, Pathogenesis	and
C10	Courouce, et al., La Gazette de la Transfusi	ion N°155-Mars-Avril (1999)	
C11	Dawson, et al., <u>The Journal of Infectious</u> Human Immunodeficiency Virus (HIV) by ( Structural Proteins, 157:149-155 (1988)	Diseases, Reliable Detection of Individuals Seropositive for Competitive Immunoassays Using Escherichia Coli-Expressed	r the HIV
C12	Devare, et al., <u>Human Immunodeficiency \and Monitoring of HIV-1 and HIV-2 Infection</u>	Virus: Innovative Techniques, Monograph in Virology, Diagration, J.L. Melnick (ed.) Basel, Karger, vol. 18: 105-121 (1990)	
C13	Homosexual Men, Acquired Immune Defi 59:267-275 (1985)	al Immunology, Precipitable Immune Complexes in Hediciency Syndrome and the Related Lymphadenopathy Syndr	ome,
C14	Gao, F., ct al., Nature, Origin of HIV-1 in th	he Chimpanzee Pan Troglodytes Troglodytes, 397:436-441 (19	999)
C15	Pathogenic Lentivirus, 277:177-179 (1985)		
C16	Goudsmit, et al., The Lancet, Expression of Cerebrospinal Fluid During Acute and Chr	of Human Immunodeficiency Virus Antigen (HIV-Ag) In Serum ronic Infection, ii:177-180 (1986)	and
C17	Griffith, et al., Journal of Clinical Microbic Virus Type 1 and Antigen at 4°C and at Roc	ology, Stability of Free and Complexed Human Immunodeficition Temperature, 33:1348-1350 (1995)	ency
C18	Gupta, et al., New England Journal of Med 310:1530-1531 (1984)	licine, Correspondence: Circulating Immune Complexes in A	IDS,
C19	Gurtler, et al., Journal of Virological Meth Different Anti-HIV Screening ELISAs and T	<u>nods,</u> Reactivity of Five Anti-HIV-1 Subtype O Specimens with Three Immunoblots, 51:177-184 (1995)	1 Six
C20	Gurtler, et al., <u>Journal of Virological Meth</u> p24 Antigen and Human Immunodeficiency	hods, Reduction of the Diagnostic Window with a New Comb v Virus Antibody Screening Assay, 75:27-38 (1998)	
C21	Gurtler, et al., <u>Journal of Virological Meth</u> (MVP-5180) From Cameroon, 68:1581-158	hods, A New Subtype of Human Immunodeficiency Virus Ty 85 (1994)	pe I
C22	Type 2, 326:662-669 (1987)	ation and Transactivation of the Human Immunodesiciency V	
C23	Haesevelde, et al., <u>Journal of Virology</u> , ( Divergent African Human Immunodeficience	Genomic Cloning and Complete Sequence Analysis of a Hi cv Virus Isolate, 68:1586-1596 (1994)	ghly
	/Jeffrey Parkin/	DATE CONSIDERED 05/30/2010	
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### Form PTO - 1449 (Modified)

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(37 CFR 1.98 (b)	)		

## OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

i		Table 1	
	C24	Hunt, et al., AIDS Research and Huma	an Retroviruses, Envelope Sequence Variability and Serologic
		Characterization of HIV Type I Group O I.	solates from Equatorial Guinea, 13:995-1005 (1997)
	C25	Kageyama, et al., Journal of Virological M	lethods, An Improved Method for the Detection of HIV Antigen in
		the Blood of Carriers, 22:125-131 (1988)	
	C26	Kanki, et al., Science, New Human T-Lymp	hotropic Retrovirus Related to Simian T-Lymphotropic Virus Type
		III (STLV-III <sub>AGM</sub> ), 232:238-243 (1986)	
	C27	Kanki, et al., Science, Human T-Lymphotro	opic Virus Type 4 and the Human Immunodeficiency Virus in West
		Africa, 236:827-831 (1987)	
	C28	Karush, F. In Comprehensive Immunolog	y, ed. R.A. Good, S.B. Day, The Affinity of Antibody: Range,
		Variability and the Role of Multivalence, 5	85-116 (1978)
	C29	Kenny, et al., The Lancet, HIV Antigen Tes	
	C30	Kessler, et al., JAMA, Diagnosis of Huma	n Immunodeficiency Virus Infection in Seronegative Homosexuals
		Presenting with an Acute Viral Syndrome,	
	C31	Ly, et al., Journal of Clinical Microbiology	, Contribution of Combined Detection Assays of P-24 Antigen and
!		Anti-Human Immunodeficiency Virus (HI)	V) Antibodies in Diagnosis of Primary HIV Infection by Routine
	_	Testing, 38(6): 2459-2461 (2000)	
	C32	Mariuzza, et al., Rev. Biophys. Chem., Th	ne Structural Basis of Antigen-Antibody Recognition, 16:139-159
		(1987)	
	C33	Mathiesen, et al., Journal of Virological Me	ethods, Acid Hydrolysis of Serum Samples to Increase Detection of
İ		HIV Antigen, 22:143-148 (1988)	
1	C34		gical Characterization of HIV-1 Group O Infection in Cameroon,
		11:445-453 (1997)	great communication and the communication,
	C35		Infection Predicted by the Quantity of Virus in Plasma, 275:1167-
1		1170 (1996)	2. Section 1 - cureiou by the Quantity by thus in 1 tusina, 275.1107-
t	C36		ions in HIV Quasispecies in Vivo are not Reflected by Sequential
	000	HIV Isolations, 58:901-910 (1989)	ions in 1117 Quasispecies in 7100 are not Reflected by Sequential
	C37		ion and Antigenicity of the Major Envelope Glycoprotein of
	057	Lymphadenopathy-Associated Virus, 144:2	
EXAMINER		Lymphauenopuny-71330ctateu virus, 144.2	DATE CONCIDENCE
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## Form PTO - 1449 (Modified)

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(37 CFR 1.98 (b))	(Use several sheets if necessary)	FILING DATE November 17, 2003	GROUP

### OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

	C38	Mulder, et al., <u>Journal of Clinical Microb</u> <i>Immunodeficiency Virus Type I RNA in</i> (1994)	iology, Rapid and Simple PCR Assay for Q Plasma: Application to Acute Retroviral	Quantitation of Human Infection, 32:292-300		
	C39	<del>                                      </del>	Phair, JAMA, Human Immunodeficiency Virus Antigenemia, 258:p1218 (1987)			
	C40	Robertson, et al., Nature, Recombination o	f HIV-1, 374:124-126 (1995)			
<u> </u>	C41	Saag, et al., Nature Medicine, HIV Viral Lo	oad Markers in Clinical Practice, 2:625-629	(1996)		
	C42	the Serum of Patients with AIDS, 224:506-				
	∞ <del>⊚4</del> 9∞∞	Schochemun, et al., Aids Testing, Springer	- Verlag, New York, Berlin, Heidelberg	JSP/ 05/30/10		
	C44	Schulz, et al., <u>The Lancet</u> , Envelope Gen Immunodeficiency Virus Infection, 2:111-1	ne-Derived Recombinant Peptide in the Ser 12 (1986)	rodiagnosis of Human		
	C45	Schupbach, et al., AIDS, Heat-Mediated Immune Complex Dissociation and Enzyme-Linked Immunosorben. Assay Signal Amplification Render p24 Antigen Detection in Plasma as Sensitive as HIV-1 RNA Detection by Polymerase Chain Reaction, 10:1085-1090 (1996)				
	C46	Sharp, et al., Biological Bulletin, Origins and Evolution of AIDS Viruses, 196:338-342 (1999)				
	C47	Simmonds, et al., <u>Journal of Virology</u> , Human Immunodeficiency Virus-Infected Individuals Contain Provirus in Small Numbers of Peripheral Mononuclear Cells and a Low Copy Numbers, 64(2):864-872 (1990)				
	C48	Steindl, et al., <u>Journal of Immunologic</u> Dissociation of HIV-1 p24 and Other An 217:143-151 (1998)	al Methods, A Simple and Robust Meth tigens from Immune Complexes in Serum	od for the Complete and Plasma Samples,		
	C49	Stephens, et al., Science, Equine Infectious Anemia Virus gag and pol Genes: Relatedness to Visna and AIDS Virus, 231:589-594 (1986)				
	C50	Stute, The Lancet, HIV Antigen In Acute H	IV Infection, 1(8532):p566 (1987)			
	C51	van Binsbergen, et al., <u>Journal of Virologi</u> Generation HIV Antigen/Antibody Assay, 8	cal Methods, Improved Performance of Ser. 2:77-84 (1999)	oconversion with a 4th		
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(37 CFR 1.98 (b))	(Use several sheets if necessary)	FILING DATE November 17, 2003	GROUP

## OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

	C52	von Sydow, et al., British Medical Journal, Antigen Detection in Primary HIV Infection, 296:238-240 (1988)
	C53	Wain-Hobson, Current Topics in Microbiology, Human Immunodeficiency Virus Type 1 Quasispecies in Vivo and Ex Vivo, 176:181-193 (1992)
	C54	Wall, et al., The Lancet, HIV Antigenaemia in Acute HIV Infection, 1(8532):p566 (1987)
	C55	Weber, et al., <u>Journal of Clinical Microbiology</u> , Reduction of Diagnostic Window by New Fourth-Generation Human Immunodeficiency Virus Screening Assays, 36(8):2235-2239 (1998)
C	C56	Zhang, et al., AIDS, Detection, Quantification and Sequencing of HIV-1 from the Plasma of Seropositive Individuals and from Factor VIII Concentrates, 5(6):675-681 (1991)
	C57	Zhu, <u>Journal of Virology</u> , Evidence for Coinfection by Multiple Strains of Human Immunodeficiency Virus Type 1 Subtype B in an Acute Seroconvertor, 69:1324-1327 (1995)
EXAMINER	/	/Jeffrey Parkin/ DATE CONSIDERED 05/30/2010
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EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.